ArthroCare®

510(k) Summary

ArthroCare® Corporation
MultiFIX® S Knotless Fixation Device

JUL 2 9 2013

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

General Information

Submitter Name:	ArthroCare Corporation
Address	7000 West William Cannon Drive Austin, TX 78735
Contact Person:	Mitchell Dhority Vice President, Regulatory and Clinical Affairs Phone: 512-358-5995 Fax: 512-895-1489
Date Prepared:	April 26, 2013

Device Name

Proprietary Name:	MultiFIX® S Knotless Fixation Device
Common Name:	Bone Anchor
Classification Name:	Smooth or threaded metallic bone fixation fastener
Device Class:	Class II
Product Code:	MBI
CFR Section:	21 CFR 888.3040

Predicate Devices

ArthroCare MultiFIX® P Knotless Fixation Device: K120096 (cleared March 27, 2012)

ArthroCare 5.5 mm SpeedScrew® Knotless Fixation Device: K081893 (cleared October 1, 2008)

ArthroCare 6.5 mm SpeedScrew® Knotless Fixation Device: K101448 (cleared June 21, 2010)

Description

The MultiFIX S Knotless Fixation Device (MultiFIX S) is a bone anchor with inserter handle designed for use in arthroscopic and orthopedic procedures. The MultiFIX S is a knotless fixation device, meaning that manually tying surgical knots is not necessary for the fixation of suture to tissue.

The MultiFIX S consists of two primary parts: a PEEK bone anchor and an anchor inserter, which is preloaded with the anchor. The anchor inserter is a disposable tool.

The entire product is packaged in a tray with a Tyvek® lid, and the finished product is sterilized by irradiation. Both the anchor and inserter are designed for single use only.

The MultiFIX S Knotless Fixation System consists of the bone anchor and associated instruments for implanting the bone anchor. In accordance with the ArthroCare Product Development Process, testing was performed to demonstrate the proposed device is substantially equivalent to the predicate device.

Mechanical testing was performed in accordance with the requirements of the FDA Guidance Document, *Testing Bone Anchor Devices*, April 1996.

Intended Use/Indications For Use

The MultiFIX S Knotless Fixation Device is indicated for use in fixation of soft tissue to bone. Examples of such procedures include:

Shoulder: Bankart Repair, SLAP lesion repair, acromio-clavicular separation, rotator cuff repair, capsule shift/capsule-labral reconstruction, biceps tenodesis, and deltoid repair

Ankle: Lateral instability, medial instability, Achilles tendon repair/reconstruction, and midfoot reconstruction

Foot: Hallux valgus reconstruction

Elbow: Tennis elbow repair, biceps tendon reattachment

Knee: Extra-capsular repairs; reattachment of: medial collateral ligament, posterior oblique ligament or joint capsule closure to anterior proximal tibia; extra capsular reconstruction, ITB tenodesis; patellar ligament and tendon avulsions

Non-Clinical Data

Bench testing was performed on both the proposed and predicate devices in accordance with the FDA Guidance Document, *Testing Bone Anchors*, April 1996. This *in vitro* testing involved insertion of the anchors in a simulated human bone substrate followed by both static and cyclic fatigue testing.

The test results demonstrate that the MultiFIX S meets its design, performance, and safety specifications. Based on the test results, the proposed device performs as intended and mechanical properties are substantially equivalent to the predicate devices when used in accordance with labeling.

Clinical Data

No clinical or animal data are included in this submission.

Summary

All testing demonstrates that the MultiFix S performs as intended and has acceptable mechanical properties when used in accordance with its labeling.

As the intended use, operating principle, materials and technological characteristics are comparable to the predicate devices, the MultiFIX S Knotless Fixation System is substantially equivalent. The minor differences between the MultiFix S and predicate devices do not raise any new questions of safety or effectiveness.

Comparison of Technological Characteristics			
Characteristics	**Proposed Device MultiFIX S**	**Predicate Device MultiFIX P (K120096)**	**Predicate Device SpeedScrew (K081893, K101448)**
Intended Use	Fixation of soft tissue to bone	Same	Same
Delivery Method	Arthroscopic and Limited Access	Same	Same
How Supplied	Sterile/Irradiation	Same	Same
Suture Material	No. 2 UHMWPE Suture	Same	Same
Anchor Material	Invibio PEEK Optima®	Same	Same

Comparison of Technological Characteristics			
Characteristics	**Proposed Device MultiFIX S**	**Predicate Device MultiFIX P (K120096)**	**Predicate Device SpeedScrew (K081893, K101448)**
Design Technology	Pound in Anchor with screw	Pound in Anchor with radial barbs	Screw in Anchor
Bone Locking Mechanism	Interference Fit (threaded screw)	Interference Fit (6 barbs)	Interference Fit (threaded screw)
Suture Locking Mechanism	Plug/Cylinder Compression	Same	Same
# of Suture Legs	2, 3 or 4	2, 3 or 4	2
Diameter of Cortical Lock	5.5 mm & 6.5 mm	4.5 mm	5.5 mm & 6.5 mm
Deployed Length	20 to 23 mm	14 to 17 mm	14 to 16 mm
Sterilization Method	Irradiation	Same	Same
Packaging	Sterile / Thermoform Tray with Tyvek Lid	Same	Same

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

ArthroCare Corporation
% Mr. Mitchell Dhority
Vice President, Regulatory and Clinical Affairs
7000 West William Cannon Drive
Austin, Texas 78735

July 29, 2013

Re: K131182
Trade/Device Name: MultiFIX® S Knotless Fixation Device
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: MBI
Dated: May 9, 2013
Received: May 14, 2013

Dear Mr. Dhority:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K 131182

Device Name: MultiFIX® S Knotless Fixation Device

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Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Casey L. Hanley, Ph.D.

Division of Orthopedic Devices